

BEFORE THE BOARD OF APPEALS AND INTERFERENCES
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ngai et al.

Serial No. 09/597,608

Filed: June 20, 2000

For: *Normalizing and Amplifying RNA*

Group Art Unit: 1655

Examiner: Taylor, J.

Attorney Docket No. B00-100-1

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Signed

Richard Osman

BRIEF ON APPEAL

The Honorable Board of Appeals and Interferences
United States Patent and Trademark Office
Washington, D.C. 20231

Dear Honorable Board:

This is an appeal from the April 20, 2001 Final Action.

REAL PARTY IN INTEREST

The real party in interest is The Regents of the University of California, the assignee of this patent application.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

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STATUS OF THE CLAIMS

Claims 1-20 are pending, claims 1-18 are allowed, and claims 19-20 are subject to this appeal.

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STATUS OF THE AMENDMENTS

Claim 20 is presented as dependent on claim 20, as opposed to the only possible antecedent kit claim, claim 19. We have submitted an amendment correcting this obvious typographical error; however, this amendment is not at issue in this appeal. Hence, all Amendments are believed to be properly before the Board.

SUMMARY OF THE INVENTION

The invention relates to a method for normalizing and amplifying an RNA population. This general method comprises the steps of:

- (a) copying message RNA (mRNA) to form first single-stranded (ss) cDNA;
- (b) converting the first ss-cDNA to first double-stranded (ds) cDNA;
- (c) linearly amplifying the first ds-cDNA to form first amplified RNA (aRNA);
- (d) tagging the 3' end of the first aRNA with a known sequence to form 3'-tagged first aRNA;
- (e) copying the 3'-tagged first aRNA to form second ss-cDNA; and
- (f) normalizing the mRNA or the first aRNA.

The only claims on appeal are directed to a kit for use in practicing this method. These kits comprise premeasured portions of a number of biochemical reagents and instructions describing the method recited above. Specification, p.3, line 30 - p.4, line 8; p.5, lines 16-18.

ISSUES

- I. WHETHER CLAIM 19 IS PATENTABLE UNDER 35USC102(b).
- II. WHETHER CLAIM 20 IS PATENTABLE UNDER 35USC103(a).

GROUPING OF THE CLAIMS

For Issue I, claim 19 shall stand as a group.

For Issue II, claim 20 shall stand as a group.

ARGUMENT

I. CLAIM 19 IS PATENTABLE UNDER 35USC102(b).

The only cited art (Stratagene Catalog, 1995, p.109) does not provide a required element of claim 19 (the required instructions), and hence cannot anticipate the claim. The sole issue in this appeal is whether the Examiner may ignore an express limitation of our claim in order to encompass the cited art.

Claim 19 is in compliance with 35USC102. The pending art rejections are mispremised upon the Examiner's refusal to consider all the limitations of our claims. In particular, the Examiner ignores the specific instructions limitations of both subject claims, arguing that "no patentable weight is given to instructions describing a method (the instructions are considered to be merely printed matter)".

The term "patentable weight" is legally meaningless. The Examiner never has discretion to disregard claim limitations. Furthermore, the Action's attempt to cite applicable law is misguided. First, the cited Haller decision was issued in 1947 - prior to the enactment of the Patent Act of 1952, now codified in Title 35 of the United States Code. Second, neither the holding nor even the cited dicta supports the Examiner's contention. And third, in *In re Gulack* (CAFC 1983) 217 USPQ401, the Federal Circuit again and emphatically reversed a Board contention that printed matter could not impart patentability:

Differences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter. ⁸ Under section 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole. If the board meant to disregard that basic principle of claim interpretation, we must reverse the rejection as a matter of law.

Gulack at p.403-404

Ironically, the Court in *Gulack* pointedly expressed its frustration with Examiners who persist in making unlawful and illogical rejections based on some notion that printed matter limitations

may be ignored.¹

Not only is the Examiner's position inconsistent with applicable law, it is inconsistent with USPTO practice. A quick search of the USPTO patent database reveals hundreds of patents issued in the past few years that clearly rely on the a printed matter limitation. We have of record highlighted claims sheets from 33 of these that clearly rely on the very same kit/instructions combination as do our claims 19 and 20.²

Claims 19 is properly limited to kits which require particular instructions. Properly construed, the claimed kit is not anticipated by the cited art. Absent a teaching within the cited art of the expressly recited method instructions, this claim is in compliance with 35USC102.

II. CLAIM 20 IS PATENTABLE UNDER 35USC103(a).

Claim 20 is in compliance with 35USC103. This rejection is similarly mispremised upon the Examiner's refusal to consider all the limitations of our claims. In particular, the Examiner ignores the specific instructions limitation of independent claim 19, arguing that "no patentable weight is given to instructions describing a method (the instructions are considered to be merely

¹ Footnote 8 of Gulack: "A "printed matter rejection" under § 103 stands on questionable legal and logical footing. Standing alone, the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art. A printed matter rejection is based on case law antedating the 1952 patent act, employing a point of novelty approach. In re Sterling, 70 F.2d 910, 21USPQ519 (CCPA 1934). The 1952 act legislatively revised that approach through its requirement that the claim be viewed as a whole in determining obviousness. Graham v. John Deere Co., 383 U.S. 1, 148USPQ459 (1966). The CCPA has considered all of the limitations of the claims including the printed matter limitations, in determining whether the invention would have been obvious. See In re Royka, 490 F.2d 981, 180USPQ580 (CCPA 1974); In re Cavrich, 451F.2d1091, 172USPQ121 (CCPA 1971). In Royka, 490 F.2d at 985, 180 USPQ at 583, the CCPA, *notably weary of reiterating this point*, clearly stated that printed matter may well constitute structural limitations upon which patentability can be predicated."

² The Examiner questions whether the recited instructions of these issued claims are providing patentability. They clearly are. Even a cursory review of the claims readily demonstrates that without the instructions, the highlighted claims of all of these patents are plainly not novel. Even the one claim selected by the Examiner, claim 2 of US Pat No.6,177,407, would clearly read on prior art angiotensin but for the recited instructions.

printed matter)". The Examiner never has discretion to disregard claim limitations. Absent a prior art suggestion of the expressly recited method instructions, this claim is in compliance with 35USC103.

Appellants respectfully request reversal of the pending Final Action by the Board of Appeals.

Appellants hereby petition for any necessary extension of time pursuant to 37 CFR 1.136(a). The Commissioner is hereby authorized to charge any necessary fees associated with this communication to our Deposit Account No. 19-0750 (order no. B00-100-1).

Respectfully submitted,
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CLAIMS ON APPEAL

19. A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.

20. A kit according to claim 20, comprising premeasured portions of oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.